Geopolitics of Access to Medicines and Intellectual Property Rights: Views from South

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Introduction

Health is approached by states from different perspectives viz. health as a development issue, health as a strategic tool, health as a trade tool, health as a human right, etc. Hence, it increasingly figures as a priority agenda in the foreign policy of states. Since the adoption of the UN General Assembly (UNGA) Resolution on Global Health and Foreign Policy in 2008, there is standing agenda item on health. This clearly shows that health is no more a technical issue, even though the US delegate reminds rest of the Member States at almost every governing body meeting of the World Health Organisation (WHO). General assembly resolution 62/33 2008 *requests the Secretary General, in close collaboration with the Director General of the World Health Organization, and in consultation with Member States, to submit to the General Assembly at its sixty-fourth session, in 2009, a comprehensive report, with recommendations, on challenges, activities and initiatives related to foreign policy and global health, taking into account the outcome of the annual ministerial review to be held by the Economic and Social Council in 2009.*[3]

The report identifies the health-related challenges that must be addressed by foreign policymakers and the key foreign policy issues that have a significant impact on health. Among the seven health-related challenges identified by the report one is "Ensuring access to and affordability of medicines".[4] There is one more identified challenge directly linked to access to medicines, i.e., Meeting the health-related Millennium Development Goals (MDGs)[5].

In the recent years, the discussion on access to medicines is no more confined to the

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[1] Co-director with Sangeeta Shashikant of the Book : Unpacking the Issue of Counterfeit Medicines. Third World Network. Malaysia, 2010, 74p.
[2] http://twnside.org.sg/

[3] GA 63/33, Global Health and Foreign Policy, Operational Para.5 available at http://www.un.org/en/ga/63/resolutions.shtml
[4] See Global health and foreign policy: strategic opportunities and challenges, Note by the Secretary-General, available at http://www.who.int/trade/foreignpolicy/FPGH.pdf
[5] ibid

WHO and the UNGA. Apart from the usual forums like UNGA, WHO, World Intellectual Property Organisation (WIPO), World Trade Organisation (WTO) and United Nations Human Rights Council (UNHRC), medicine issue is figuring in many international and regional organisations like United Nations Office on Drugs and Crime (UNODC), World Customs Organisation (WCO), International Postal Union (IPU), International Criminal Police Organisation (INTERPOL), Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), etc. This growing interest shown by many of these organisations is not driven by public health considerations.

Now let us look at some of the critical challenges with regard to ensuring access to medicines in the context of international intellectual property (IP) regime. This issue is approached here from a Third World perspective in the light of international obligations/responsibilities with regard to the right to health and the right to development.

Firstly, we will discuss the issues of access to medicines in the context of human rights and development discourses. Secondly, we will look at certain concrete examples from the recent past of the attempts of developed countries at various international organisations with regard to access to medicines. Thirdly, we will examine the truth behind popular narratives that lead to the standard response of developed countries on access to medicines. Fourthly, we will look at the key barriers in fulfilling the obligations with regard to access to medicines, with a special focus on the international legal obligation in the area of intellectual property rights (IPRs), trade and investment.

Access to Medicine: International Legal and Policy Context

Health is considered as a development issue and no more discussed in isolation. The 66th World Health Assembly (WHA) adopted a resolution titled 'Health in the Post 2015 UN Development Agenda', which urges Member States *"to ensure that health is central to the post 2015 UN Development Agenda*".[6] Further, discussions are on universal health coverage. We also hear many jargons reflecting more or less the same idea of multi-sectoral approach, health for all and social determinants of health. Access to affordable medicine is very much an issue to address the global health effectively. There is a shared understanding in this regard, which is reflected in various documents. Let us look at some of these relevant documents.

The UNGA Resolution on Global Health and Foreign Policy adopted in 12 December

[6] WHA 66.11, Health in the post-2015 UN development agenda, available at http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R11-en.pdf

2012, *Recognizes that improving social protection towards universal coverage is an investment in people that empowers them to adjust to changes in the economy and in the labour market and helps support a transition to a more sustainable, inclusive and equitable economy*. [7]

This resolution *Noting with particular concern that for millions of people the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote, that millions of people are driven below the poverty line each year because of catastrophic out-of-pocket payments for health care, and that excessive out-of-pocket payments can discourage the impoverished from seeking or continuing care.*[8]

Further the resolution acknowledges that universal health coverage implies that all people have access, without discrimination, to nationally determined sets of the needed promotive, preventive, curative and rehabilitative basic health services and essential, safe, affordable, effective and quality medicines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poor, vulnerable and marginalized segments of the population[9].

At the Rio Political Declaration on Social Determinants of Health, the Member States of WHO pledged to *Promote access to affordable, safe, efficacious and quality medicines, including through the full implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.*[10]

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises the right to health as human right. Article 12 (d) clearly states the *steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the creation of conditions which would assure to all medical service and medical attention in the event of sickness.*

During the last two decades, many progress has been achieved in advancing access to medicines within the human rights framework through the work of Committee on Economic, Social and Cultural Rights, Office of the High Commission on Human

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[7] See resolution Global Health and Foreign Policy, available at http://www.un.org/ga/search/view_doc.asp?symbol=A/67/L.36&referer=http://www.un.org/en/ga/info/draft/index.shtml&Lang=E

[8] Ibid

[9] ibid

[10] Rio Political Declaration on Social Determinants of Health , available at http://www.who.int/sdhconference/declaration/en/

Rights, UNHRC and the work of the two Special Rapporteurs on *the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.* In the past, the two Rapporteurs have prepared many reports. [11]The UNHRC adopted resolutions on the access to medicine including the *Resolution on Access to Medicine* adopted in the on 13th June 2013.

The latest report of the Rapporteur on Right to Health is on access to medicines[12]. This report, which was introduced at the 23rd session of the HRC on 27 May "identifies and analyses challenges and good practices with respect to access to medicines in the context of the right-to-health framework".[13] It uses the key human rights framework on access to medicines, i.e., availability, accessibility, acceptability and quality to analyse the international and national determinants to access to medicines.

In the first section of the report, the rapporteur reviews the international legal framework as it applies to access to medicines. The rapporteur clearly states: 'that access to affordable and quality medicines and medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central elements for the enjoyment of the right to health". Further, the rapporteur 'calls upon the States to shift from the dominant market-oriented perspectives on access to medicines towards a right-to-health paradigm in promoting access to medicines".

In the second section, the rapporteur identifies key determinants of access to medicines and discusses challenges and good practices with respect to each aspect. The key determinants identified by the rapporteur in the report are: local production of medicines, price regulations, medicines lists, procurement, distribution, rational and appropriate use and quality of medicines.

It is very clear that there are various determinants on access to medicines. However, international obligations---IP protection, trade and investment---act as the main barriers to ensure sustained availability of affordable medicines. International obligations in these three areas left little policy space for developing countries to pursue a self-sufficiency strategy in the production of medicines. In other words, the international obligations in the area of IP, investment and trade incapacitate developing countries from fulfilling their obligations on right to health and right to

[11] Intellectual Property and Access to Medicines (Doc.E/CN.4/2004/49/Add.1), The Human Right to Medicines (Doc.A/61/338, pp.10–18 (2006)), Health Systems and the Right to the Highest Attainable Standard of Health (Doc.A/HRC/7/11 (2008), Guidelines for Pharmaceutical Companies (Doc.A/63/263 (2008)), Mission to GlaxoSmithKline (Doc.A/HRC/11/12/Add.2 (2009)).

[12] Available at http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A-HRC-23-42_en.pdf

[13] ibid

enjoy the progress of science guaranteed under ICESCR.

Both the trade and investment rules took away much of the policy space to develop local manufacturing in individual developing countries or regional hubs. The trade liberalisation through multilateral and bilateral trade agreements during the last 18 years or so took away much of the policy space on tariffs. The policy advice in this area focuses on the elimination of tariffs to facilitate access to medicines. This is a shortsighted advice and it took away an important tool to encourage local production.

Similarly, the infamous Bilateral Investment Treaties (BITs) armed with investor state dispute mechanism considerably reduce the policy space to induce a local production in developing countries. For instance, some of these treaties prohibit performance requirements, which is one of the tools used by developed countries to build a manufacturing sector. BITs also have interface with IP which we will look at later.

Since the focus here is on the IP protection, let us look at a few examples illustrating the typical response of developed countries in four international organisations while discussing concerns related to medicines.

Developed Country Response

Last week, as mentioned earlier, UNHRC adopted a resolution on access to medicine clearly acknowledging the rapporteur's report on the right to health. The resolution was adopted through voting. Both the EU and the US abstained from voting. The main reason for the disagreement was on the US proposal to limit the scope of the resolution to only essential medicines. As per the US proposal, the OP5 (a) would read:

To implement or, where they do not exist, to establish national health frameworks that ensure access for all, without discrimination, to medicines, ***in particular essential medicines*** *that are affordable, safe, efficacious and of quality*.

Further, the US also proposed the word 'appropriate' to the heavily diluted provisions on use of flexibilities.

To promote access to medicines for all, including through the use, to the full, of the provisions of the TRIPS Agreement which provide flexibility for that purpose, recognizing intellectual property protection is important for the development of new medicines as well as the concerns about its effects on prices.

The international obligations on access to medicines are not restricted only to essential medicines. The US proposal to restrict the scope of the resolution to essential medicines is an attempt to minimise the access to medicines.

It is very clear that confining access only to essential medicines will not address the health needs of developing countries. Let us look at this issue a little deeper.

1. The essential medicines list, as the name shows, is only a list of bare minimum medicines with proven use. Therefore, it always contains a list of old medicines without patent protection. A WHO study shows that nearly 96 per cent of medicines in the WHO list of essential medicines are out of patents. In fact, the US claimed in WIPO Standing Committee that only 4 per cent of medicines in the WHO List of Essential Medicines (EML) are currently protected by patents, and implies that the paucity of patented drugs in the WHO list is evidence that patents on drugs are not important for patients. Therefore, it is important to expand the scope of access to medicine concept beyond essential medicines.
2. The selection criteria for essential medicine at WHO include cost effectiveness. Thus the patented medicines with high costs are mostly excluded from the essential medicines list.
3. A Knowledge Ecology International (KEI) research note states: In 2011, Paul Miano examined 100 cancer drugs considered important by the US NIH (For 100 new molecular entities (NMEs) on the NCI alpha list of cancer drugs and vaccines, see *Cancer: Approval, Ownership, Market Structure and Placement* on WHO Model EML). According to Miano, more than half of the 100 important cancer drugs were first registered for sale by the US FDA after January 2000. In the WHO Model EML, 2011, there were zero cancer drugs on the main list, and 20 products on the complementary list. The newest product on the WHO EML, that was among the NIH's 100 most important products, which was registered by the FDA in 1996, and all of the EML cancer products were off patent. To suggest that no patented cancer drugs are 'essential' is to say that saving the lives of poor people who have cancer is not essential or that the products were just too expensive to justify their use in resource-poor settings. What is surprising is that when the products go off patent, they often find themselves on the list.

Hence, the motivation behind the US proposal is to keep the human rights framework away from patented medicines. While doing it, the US and the EU prevent people in developing countries from the enjoyment of another human rights guaranteed under Article 15.1 (b) of ICESCR. Article 15 1(b) states: *the States Parties to the present Covenant recognize the right of everyone to enjoy the benefits of scientific progress and its applications*.

Let us now look at another example, i.e., extension of TRIPS non-implementation transition period in least developed countries (LDCs). Article 66.1 states "*The Council*

for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period." However, the LDCs after the submission of their duly motivated request were forced into a negotiation with developed countries, the so-called green room excluding the vast majority of WTO membership. This is a clear exercise of power to bend the rules.

Another issue is related to the nature of obligation contained in the decision. One of the important issues of negotiation was whether LDCs can rollback the existing level of IP protection during the non-implementation transition period. There is no obligation in the decision against the roll back. It clearly state*s "Recognizing the progress that least developed country Members have already made towards implementing the TRIPS Agreement, including in accordance with paragraph 5 of IP/C/40, least developed country Members express their determination to preserve and continue the progress towards implementation of the TRIPS Agreement. Nothing in this decision shall prevent least developed country Members from making full use of the flexibilities provided by the Agreement to address their needs, including to create a sound and viable technological base and to overcome their capacity constraints supported by, among other steps, implementation of Article 66.2 by developed country Members*."

However, after the adoption of the decision, the EU issued a press release stating that "Where least-developed countries voluntarily provide some kinds of intellectual property protection even though they are not required to do so under the TRIPS Agreement, they have committed themselves not to reduce or withdraw the current protection that they give". LDCs expressed their determination, but not committed.

In November 2012, the EU and the US opposed any further process to take forward the recommendations of Community Epidemiology Work Group (CEWG) to establish an international framework for coordination, prioritisation and sustainable funding to meet the R&D needs of developing countries. The mechanism is to follow an open innovation approach where the R&D outcomes are free for further use without any legal and contractual obligations. This new model would have delinked the cost of R&D from the price of the product and put in practice a new R&D model to address the unmet R&D needs of developing countries. This is important because the patent oriented R&D model failed to deliver medicines and it predominantly affected the developing countries.

In 2011, the EU opposed the reference of the political declaration on Non-Communicable Diseases (NCDs) in the Doha Declaration. Further, developed countries opposed the detailed discussion on public health and patents in the Standing Committee on Patents at WIPO. The US even proposed that there is no

impact of patented medicines and only 4 per cent of medicines in the essential list is covered by patents.

Further, developed countries gave their consent for the adoption of the Doha Declaration on Public Health and the TRIPS Agreement, which contain the political consensus to use the TRIPS flexibilities to meet the public health needs. However, after the adoption of the Declaration developed countries did everything to neutralise the use of TRIPS flexibilities. The TRIPS plus provisions were pushed through Free Trade Agreement (FTA) or technical assistance to ratchet up the IP protection and enforcement standards. The EU even put a strategy in place to enhance IP enforcement standards in Third World countries above TRIPS level, which eventually resulted in the mushrooming of anti-counterfeit legislations in East Africa.

It needs mentioning that whenever developing countries used TRIPS flexibilities, developed countries termed it as a misuse. The responses of the EU and the US on the issuance of compulsory licence (CL) in Thailand are some of the instances.

All these examples clearly show that when it comes to IP, developed countries not only want the status quo but also further upward movement of IP protection and standards, and at times even beyond their own legal requirements.

IP and Access to Medicines

It is important to mention that access to medicines cannot be addressed effectively without addressing the issue of IP protection and enforcement. Patent is the most important form of IPR, which prevents competition and availability of medicines at competitive prices in the market.

Excessive IP protection incapacitates states from fulfilling their obligations on the right to health in the following ways:

- It eliminates competition in the pharmaceutical market and leads to monopoly prices
- It retards innovation and encourages rent seeking through multiple patents on medicines
- High prices of patented medicines restrain states from making public provisioning of medicines
- It incapacitates states from fulfilling their obligation under Article 15.1 (b), which states that States Parties to the present Covenant recognize the right of everyone to enjoy the benefits of scientific progress and its applications.

Apart from the patent, trademark and data exclusivity protection are also used by pharmaceutical companies to maintain their monopoly in the market. However, we will focus only on patent protection in the discussion here.

As mentioned earlier, IP issues related to medicines are not confined to TRIPS alone though it is the central agreement. TRIPS establishes the common minimum obligations on developing countries with regard to patent protection on pharmaceutical patents. It obligates WTO Member States to provide 20 years' product patent protection and also imposes certain procedural restrictions to grant CL. Utilisation of the TRIPS flexibilities is advocated as a way forward to find a balance between obligations on the right to health and access to medicines. The Doha Declaration and so many resolutions and declarations stress the need for the use of TRIPS flexibilities. However, it is not a viable option for many countries.

Limitations on the Use of TRIPS Flexibilities

For the developing countries, incorporation of TRIPS flexibilities (public interest safeguards) in the domestic legislation is the dominant strategy for balancing the public and private interests while implementing the TRIPS-compliant patent regime. However, it is not an easy task as this strategy is based on at least the following assumptions:

a) Every country enjoys the same level of technological capabilities, including the manufacturing capacity in the pharmaceutical sector;

b) There is a shared understanding among the developing countries and LDCs regarding the nature of TRIPS obligation and the technical skill to incorporate those flexibilities in the domestic law;

c) It assumes the existence of institutional and administrative mechanisms in the developing countries to make use of the TRIPS flexibilities after their incorporation in the domestic law; and

d) There is complete legal and political consensus on the TRIPS implementation strategy in the developing countries, and there is little political interference from the developed countries while incorporating TRIPS flexibilities in the domestic legislation. In other words, it is assumed that every developing country has the same level of political will in the implementation of TRIPS flexibilities.

The vast majority of the developing countries and all LDCs lack the manufacturing capacity in the pharmaceutical sector. Moreover, experience of the past 18 years shows that there is considerable degree of political interference and propaganda against the use of TRIPS flexibilities like CL or government use.[14] It is hard to find a single developing country in which all the four assumptions hold true.

However, the success of the TRIPS flexibilities in addressing the question of access to

[14] Developed country governments exhort political pressure on developing countries against the use of TRIPS flexibilities like compulsory licence. See Ellen t' Hoen, *The Global Politics of Pharmaceutical Monopoly Power* (Diemen: AMB Publishers, 2009), pp.44-58.

affordable medicines mainly depends on three factors: a) the incorporation of flexibilities in the domestic law; b) the manufacturing capability of a country; and c) the political will to use the public interest safeguards provided in the domestic law.

The TRIPS flexibilities do not exist in vacuum and therefore need to be incorporated in the domestic patent law. This requires development-oriented understanding of the TRIPS obligations and the technical knowledge to translate the flexibilities into the domestic patent law.

The existence of a vibrant and dynamic domestic generic industry (in public or private sector) is essential to make use of the flexibilities contained in the domestic patent law. In the absence of domestic generic industry, actual use of TRIPS flexibilities depends on the domestic law of another country having generic industry. The political will of governments plays a crucial role in the actual use of public interest safeguards provided in the law. Often the developing countries would come under tremendous pressure from pharmaceutical MNCs and their host governments against the use of public interest safeguards. There are only a few countries like India, which satisfy the above-mentioned conditions to a certain extent. Developed countries do exert tremendous political pressure on developing countries.

There is little use of TRIPS flexibilities in vast majority of developing countries. For instance, let us look at a Public Library of Science (PLOS) article on CL. "*Country- and product-specific searches were used to verify government participation, resulting in a final database of 24 verified CLs in 17 nations. We coded CL episodes in terms of outcome, national income, and disease group over three distinct periods of CL activity. Most CL episodes occurred between 2003 and2005, involved drugs for HIV/AIDS, and occurred in upper-middle-income countries (UMICs). Aside from HIV/AIDS, a few CL episodes involved communicable disease, and none occurred in least-developed or low-income countries."*

TRIPS has contributed nothing significant to meet the heath needs of developing countries. There is no evidence to show that TRIPS Agreement is resulting in an increasing investment in R&D to meet the needs of developing countries. A recent joint study by the Drugs for Neglected Diseases Initiative (DNDi) and Medecins Sans Frontieres (MSF) reveals: *Of the 756 new drugs approved between 2000 and 2011, 29 (3.8%) were indicated for neglected diseases, even though the global burden of disease is estimated at 10.5%. Of these, only four were new chemical entities (NCEs), three of which were for malaria, with none for TB or neglected tropical diseases (NTDs). Moreover, as of December 2011, only 1.4% of a total of nearly 150,000 registered clinical trials were focused on neglected diseases, with very few of these*

trials for NCEs.[15]

It is also true that TRIPS Agreement resulted in the increase of number of patents across the world including developed countries. However, the introduction of new chemical entities (NCEs), excluding "me-too" drugs, can be counted in fingers. Recent studies show that only a few medicines introduced in the market have substantial therapeutic efficacy.

Moreover, there is hardly any evidence to show that TRIPS Agreement has resulted in increased investments in manufacturing in developing countries. On the contrary, there are evidences to show that TRIPS has resulted in increase in importation of finished goods.

All these show the negative effects on access to affordable medicines. In short, TRIPS Agreement obligates countries to provide property rights to pharmaceutical MNCs without any reciprocating benefits and compromises the ability fulfil the key human rights obligations including the right to health.

Against this background, it is important to consider the recommendation of the UNDP-appointed Global Commission on HIV and the Law, which consisted of 14 eminent individuals acting in their individual capacity. The Commission recommended suspension of the TRIPS Agreement. It observed that:

"TRIPS has failed to encourage and reward the kind of innovation that makes more effective pharmaceutical products available to the poor, including for neglected diseases. Countries must therefore develop, agree and invest in new systems that genuinely serve this purpose, prioritising the most promising approaches including a new pharmaceutical R&D treaty and the promotion of open source discovery".

Against this finding, the Commission recommends:

The UN Secretary-General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors. Such a body should include representation from the High Commissioner on Human Rights, WHO, WTO, UNDP, UNAIDS and WIPO, as well as the Special Rapporteur on the Right to Health, key technical agencies and experts,

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[15] *DnDI and MSF, Medical Innovation for Neglected Patients, 2012 Available at* *http://www.doctorswithoutborders.org/events/symposiums/2012-lives-in-the-balance/assets/files/Medical-Innovations-for-Neglected-Patients.pdf*

and private sector and civil society representatives, including people living with HIV. This re-evaluation, based on human rights, should take into account and build on efforts underway at WHO, such as its Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property and the work of its Consultative Expert Working Group. Pending this review, the WTO Members must suspend TRIPS as it relates to essential pharmaceutical products for low- and middle-income countries.

For an assessment of TRIPS Agreement, 18 years is more than enough. Unlike the initial perception, TRIPS is turning out to be a slippery slope. While developing countries are struggling to cope up with the TRIPS Agreement, the limited policy space is further curtailed by imposing TRIPS plus obligations on developing countries through FTAs.

TRIPS Plus Provisions

The logic of TRIPS plus provisions is to limit the scope of flexibilities available under the TRIPS Agreement. A recent working paper prepared by WTO states that some 54 Regional Trade Agreements (RTAs) were found to contain at least one of the pharma-related provisions. Further, it also found that the provision most frequently included in RTAs relates to patentability criteria and exclusions, with over one-quarter of the 165 agreements in the sample. The report says:

> *RTAs involving the United States are primarily responsible for this trend. Indeed, the majority of the United States' RTAs incorporate pharma-related provisions, many of which include several provisions on the eleven sub-categories covered by this study. While far behind the United States, Mexico also contributes significantly to the prevalence of pharma-related provisions in RTAs involving parties from the Americas. EFTA members are the trading bloc that includes pharma-related provisions in their RTAs more frequently, although the number of such provisions in a typical EFTA agreement is not high.*

As a consequence, many of the RTAs involving the US contain provisions that can result in longer than normal periods of market exclusivity. These provisions may delay the market entry of generic drugs through measures such as data exclusivity, the patenting of new uses and patent term extension. The delay in patent expiration and the market entry of generic drugs will impact on the ready access to medicines.

Let us now look at the IP enforcement initiatives which compromise access to medicines.

IP Enforcement Initiatives

All attempts to conflate IP with the quality of medicine are part of the IP enforcement initiatives. There is a general tendency recently that states 'counterfeit medicines kill the patient'. What is not told is that the term 'counterfeit' is defined in the TRIPS Agreement to refer to a special type of trademark infringement. We know that an infringement of trademark per se does not kill the patient, if there is no compromise in the quality, safety and efficacy (QSE) of medicine.

There are multiple actors at the national, regional and international levels. At the international level, WCO, INTERPOL, UNODC, WHO, etc. are active. The IP enforcement initiatives by many of these organisations are based on industry data and not backed by any independent and verifiable data.

Most of these international organisations are using a particular terminology. Each one of them has more or less started using the term 'counterfeit' and some are now slowly moving away from the term and now started using new terminology such as fraudulent medicine, falsified medicine, etc. or using the new terminology along with the old terminology 'counterfeit'. However, there is no clarity regarding the meaning and content of these terms.

It is important to note that technically each of these terms, sub standard, spurious, falsely labeled, falsified, fraudulent, fake, illegal, etc., are not interchangeable and has its own meaning. Hence, we need to develop a shared understanding on the meaning and content of these terms. It is not legally and practically feasible to bring all actions, conducts or even elements, which lead to the compromise of QSE of medicines.

It is important to mention the work programme of INTERPOL, which is serving the interest of pharmaceutical MNCs through its actions on pharmaceutical crime. This programme was created in 2011, and till then INTERPOL's programme was part of its activities on IP crime unit. INTERPOL indulges in propaganda without any verifiable data. For instance, according to INTERPOL, pharmaceutical products, which violate any law in a country, will fall within the definition of pharma crime. This may include violation of customs laws or tax laws. This does not mean that all the medicines seized by various INTERPOL operations are of compromised quality. However, INTERPOL projects pharma crime as a major public health threat without explaining the scope of its definition.

The IP enforcement by the EU has resulted in the seizure of generic medicine in transit at European transit points and resulted in the distribution of medicines in various developing countries. However, the EU is still silent on the issue and there is

no clarity with regard to this.

Industry Capture

The primary reason for the lopsided policy is the industry capture of policy making. Let us look at some of the new examples from the US.

A recent submission by Pfizer before the House Subcommittee on trade thus requested: *" The U.S. government should review all available policy tools in light of India's deteriorating intellectual property environment. The U.S. government should pursue a robust trade agenda that includes strong intellectual property protections that build on the Korea-U.S. Free Trade Agreement and U.S. law, including robust provisions in the Trans-Pacific Partnership Agreement (TPP)".*[16]

After a few days, 17 industry associations, including pharma, of the US wrote to President Obama that *Administrative and court rulings have repeatedly ignored internationally recognised rights – imposing arbitrary marketing restrictions on medical devices and denying, breaking or revoking patents for nearly a dozen lifesaving medications.* Further it requested *the US government to ask India to fall in line at the highest level and also join hands with the EU and other 'likeminded economies'.* If nothing works, they wanted *the US to use 'trade tools and diplomatic engagement', which in simple terms means restrictions, possible embargoes and exploitation of strategic bilateral platforms*[17]*.*

The obvious reference is to the cancellation of patents, especially the decision of the Indian Supreme Court to deny patent to Novartis' imatinib mesylate, a medicine used for the treatment of chronic myelogenous leukemia (CML). The patent was denied on the ground of lack of novelty and non-satisfaction of the requirement of Section 3(d). Section 3(d) regulates the patenting of known substance, which is a flexibility clearly well within the TRIPS Agreement.

Thus the truth is far from the industry claim. The popular narrative is that the industry is facing extreme competition from developing countries like China and India. Hence, pharmaceutical industry needs the protection of host governments. Let's look at the size of the industry and the competition from the developing country market. This is the only industry showing minimum impact of ongoing

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[16] Written Testimony of Roy F. Waldron Chief Intellectual Property Counsel Pfizer Inc. Before the House Committee On Ways And Means Subcommittee On Trade Hearing on U.S.-India Trade Relations: Opportunities And Challenges, available at http://waysandmeans.house.gov/uploadedfiles/pfizer_testimony31313.pdf

[17] See Willam New, Members Of US Congress Seek Pressure On India Over IP Rights available at http://www.ip-watch.org/2013/06/20/170-members-of-us-congress-pressure-india-on-ip-rights/?utm_source=post&utm_medium=email&utm_campaign=alerts

financial crisis. The joint study by the WTO, WIPO and WHO shows that developing countries account only 20 per cent of the global medical products and 30 per cent of the global imports. This shows that substantial percent of the trade is happening within developed countries.

The top 20 drugs in the US accounted for USD 319.9 billion in sales in 2011. While India's total market size of pharmaceutical industry is valued around USD 12 billion. The total value of India's pharmaceutical market, including export and domestic market, is less than USD 19 billion.

The developed countries still constitute nearly 82 per cent of the global pharmaceutical market. According to the WHO's *World Medicines Report 2011*, 16 per cent of the world's population living in high-income countries accounts for over 78 per cent of global expenditures on medicines.

Further, there is no logic of high protection of IP and recovery of R&D cost from developing country markets. Much of the value of the new drugs is recovered from the developed country markets. Recovering R&D costs from developing country markets has no economic rationale. On the contrary, due to the lack of effective social security system for people in developing countries, medicine expenditure there is largely out-of-pocket (OOP) expenditure. Often this OOP expenditure turns out to be catastrophic payment and pushes people into poverty. According to a WHO study, worldwide about 150 million people face catastrophic health-care costs in an year, because of direct payments such as user fees, while 100 million are driven below the poverty line. Medicine is an important component of this catastrophic payment. It does not make economic sense to expect the recoup of R&D expenditure from developing country markets. In other words, the level of patent protection is of fewer consequences for pharmaceutical MNCs in terms of their revenue.

This clearly shows that industry wants to preserve the market in developed countries showing the boggy of competition from the developing countries. Further, it wants to maintain the high level of profit without getting interrogated by people in developed countries by pointing out the far less price of medicines by generic companies in developing countries. As a result, the people in developing countries are denied the right to health and at times handed over a death sentence for the protection of profit.

Let's also remind that the TRIPS Agreement itself is the product manufactured and sold by the industry to the EU trade and the US policy makers, which is now legitimising corporate greed. This is not at all a sustainable model, even in Europe,

especially in the light of ongoing euro zone crisis.

The point to be noted here is that foreign policy in the area of trade, health, investment and IP should be made on the basis of empirical evidence. It should not be solely based on the industry inputs or global consultancy firms. Foreign policy should take into consideration of the competing interests. Further, certain values and norms should not be made negotiable. The right to health should not be compromised to pursue corporate interest.

Mechanisms should be made to insulate foreign policy making from industry capture. Decision making on foreign policy in these areas should be transparent and accountable. Further, it is also important to hold the corporates accountable in their home country for their acts of violation of human rights including the right to health. This accountability mechanism should be legally enforceable, including for imposing criminal penalty.

Conclusions

Let us conclude the discussions by focusing on the following key points to ensure access to medicines:

- Prevent the industry capture of foreign policy
- Make foreign policy based on independent and verifiable evidence
- Ensure transparency and accountability in foreign policy making
- Consider the right to health as a non-negotiable tool to pursue economic interest
- Carry out an independent assessment of TRIPS Agreement on access to medicines with an objective to amend the agreement to address the concerns of developing countries
- Revamp the FTAs that contain TRIPS plus provisions.